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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,694	12/12/2001	Shobha Shakher Puntambekar	ITW 13471\TEM 0001 PA	9163

7590 06/02/2004

Killworth, Gottman, Hagan & Schaeff, L.L.P.  
Suite 500  
One Dayton Centre  
Dayton, OH 45402-2023

EXAMINER
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CROSS, LATOYA I

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/021,694	Applicant(s) PUNTAMBEKAR	
	Examiner LaToya I. Cross	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on March 5, 2004.

Claims 1-26 are pending.

#### *Withdrawal of Rejections from Previous Office Action*

- The anticipatory rejection over Read is withdrawn in view of Applicants' amendment to claims deleting the dyes taught by the reference.

#### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-8, 12-17, 20, 21 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by WIPO publication WO 01/86289 to Patel.

Patel teaches a color changing steam sterilization indicator. The steam indicator comprises a dye as the indicator. The dye may be Chicago Sky Blue, direct red 75, Evan's blue, nitro red or naphthol blue black, as recited in claim 1 (Table 1, pages 11-14). For monitoring steam sterilization, Patel teaches that the steam temperatures of 60-70oC (page 24, Example 2). With respect to claim 4, the reference teaches that the indicators are not affected by ethylene oxide, dry heat or radiation (page 23, line 21-22, 28). With respect to the amount of indicator

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used, Patel teaches 0.1-30 w/w% (page 22, lines 31-32). Further, a neutral dye or pigment may be incorporated into the indicator which does not change color with steam, such as one that changes from colorless to blue, as recited in claims 12-14 (col. 14, lines 23-30). At page 6, page 7, lines 3-4, the reference teaches that the formulation may be in the form of an ink. With respect to the presence of thickening agents, and binders, Patel teaches polymers as binders and wax and carboxymethyl cellulose as thickeners (page 19, lines 18-27; page 20, lines 21-31). With respect to the presence of an additional dye, Patel teaches that the indicator may have additional dyes different from the primary dye. The reference teaches Congo red and Benzo purpurin (page 12, lines 12 and 21).

Therefore, for the reasons set forth above, Applicants' claimed invention is deemed to be anticipated, within the meaning of 35 USC 102 (e) in view of the teachings of Patel.

### *Claim Rejections - 35 USC § 103*

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 9-11, 18, 19, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel in view Read (US 4,298,569).

The disclosure of Patel is described above. Patel differs from the instant invention in that there is no disclosure of the presence of a buffer, a brightener and polyvinyl alcohol.

Read teaches a steam-formaldehyde sterilization indicator comprising an indicator dye and other additives that enhance the indication of sterilization. First, Read teaches using a buffer to maintain the pH at 4-6 so that no color change results when the indicator is exposed

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to ethylene oxide (col. 2, lines 36-44). Next, Read teaches brighteners such as gelatin and polyvinyl alcohol for binding and stabilizing (col. 3, lines 40-50).

It would have been obvious to one of ordinary skill in the art to incorporate a buffer, brighteners and polyvinyl alcohol into the indicators of Patel, to provide the indicator with enhanced sensitivity to only steam, and to enhance the ability of the indicator provide an observable change in response to sterilization.

5. Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patel and Read as applied to claims 1-23 and 26 above and further in view of US Patent 5,258,065 to Fujisawa.

The disclosure of Patel and Read is discussed above. Neither reference discloses a preservative in the indicator composition.

Fujisawa teaches sterilization indicator compositions. The reference notes that components such as preservatives are conventionally incorporated into ink compositions for sterilization indicators. Sorbic acid is a commonly used preservative in these applications. It would have been obvious to one of ordinary skill in the art to incorporate a preservative into the indicator composition of Read to allow the composition to be more storage stable and maintain the integrity of the components.

### *Response to Arguments*

6. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700